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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,658	01/09/2002	Eric N. Olson	MYOG:024USC1	7444

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/043,658	OLSON, ERIC N.	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *2/23/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 4, 9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4 and 9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation of 09/438,075, filed November 10, 1999, now US Patent 6,372,957, which claims benefit to provisional applications 60/107,755, filed November 10, 1998 and 60/108,083, filed November 12, 1998.

Claims 1, 4 and 9 are pending.

Election/Restrictions

As indicated previously, Applicant's election without traverse of group III, claims 4 and 9, in the reply filed on April 5, 2004, was acknowledged, and claims drawn to non-elected inventions have been cancelled.

However, the restriction requirement was set forth as a linked invention and that restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C.

121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP ' 804.01.

Claim Objections

Claim 1 stands objected to because 1 is broader than the elected invention which was Group III, drawn to a method of treating hypertrophy in a cardiomyoctye comprising the steps of (1) decreasing the expression of MEF2 gene; and (2) further decreasing the expression of a gene that is upregulated by MEF2.

Applicants have not addressed the basis of the objection, and stands for the reasons of record.

While it is noted that claim 1 is a linking claim, however this claim and subject matter has not been found allowable. Accordingly, the scope of the claim should be amended to reflect the elected invention.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4 and 9 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant summarizes the rejection as having two aspects. First, the ability to extrapolate the role of MEF2C to other isoforms in or for hypertrophic signaling. More specifically, pointing to the post-filing reference of Xu *et al.* it is argued that the art provides evidence that MEF2A behaves similar to MEF2C in transgeneic mouse models. Second, that even though MEF2C appears to be involved with hypertrophy, the office questions whether there is sufficient and specific evidence of this being a target for methods of efficient treatment methods. Applicants note that the office ahs stated that working examples are not required, but later indicated that such proof/experiments are required. Applicant summarizes the basis of the claimed invention and points to the specification for support of enabling disclosure. See Applicants amendment, pages 3-5. Applicant's arguments have been fully considered, but not found persuasive.

Initially, examiner does acknowledge that that working examples are not required for an enabling disclosure, however it is maintained that the specification does have to be enabling. The cited portion of the office action related to gene therapy in general, and how the present specification does not address art recognized problems for gene delivery and providing relevant expression levels for any gene in methods of treatment. In this case, page 8 is commenting on art recognized problems that the present specification does not address. The present specification relies on the art for practicing and thus is subject to the shortcomings in the art. Working examples are not required to over-come the obstacles, but at least some guidance in the specification would be required for the skilled artisan to overcome these problems for

methodology related to gene therapy. In this case, the claims are very broad encompassing "inhibiting the function of MEF2" by any means. The argument is made that this breadth is not enabled, and only portions of the rejection focus on potential gene therapy protocols consistent with the animal model provided.

Turning to the more salient issue of the rejection to whether the animal model supports the basis of the invention and thus methods of treatment, it is maintained that methods of simply blocking MEF2 would be insufficient to treat hypertrophy. Again, the examiner does not contest that MEF2 is in the signaling pathway during hypertrophy, however given the complexities of the process there is insufficient evidence that inhibiting MEF2 would treat cardiac hypertrophy. Supporting this position is the post-filing art of Xu *et al.* provided by Applicant. Xu *et al.* provide a detailed analysis of the complexities of hypertrophy, and the role of MEF2A and MEF2C, concluding that "MEF2 is unlikely to be a significant downstream hypertophic effector of calcineruin in the heart" (page 9, bottom of second column), and that calcineurin-directed hypertrophy is independent of that of MEF2A (page 2, second column). Further, the role of MEF2 is not independent of HDAC in the promotion of cardiomyopathy (page 10, first column). The instantly claimed method is based in part on the up-regulation of the MEF2 during hypertrophy and the important role of MEF2C in heart growth and development, however, the instant disclosure fails to provide a clear correlation that decreasing any MEF2 family member will affect hypertrophy and fails to provide any specific guidance to what further genes to target for inhibition.

A third issue not specifically addressed in the instant response is in regard to actually practicing the method, and the materials required. Previously, Applicant has argued that while it

"may be true that inhibiting MEF2 to treat hypertrophy was not well known at the time the present application was filed" but that recent results validate the paradigm on which the instant invention is based (prior amendment page 4). Even if the Examiner agrees that the paradigm for a role for MEF2C there is insufficient to enable the method of treatment as presently claimed. In the context of the claimed invention of treatment, the specification provides no starting materials to practice the claimed invention, and no guidance on affecting the treatment with any particular agent. As noted previously, in the findings of the Robins court, in a unpredictable area of science an enabling disclosure commensurate in scope of the claimed invention is required (*In re Goodman*, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing *In re Vaeck*, 20 USPQ2d at 1445 (Fed. Cir. 1991). In this case, no materials that would be required to practice the breadth of the claims for "inhibiting the function of MEF2" (claim 1) are provided. By way of example, claim 9 was discussed in the context of a starting material and the methods required for delivery in gene therapy protocols. Again, the breadth of the claims encompass inhibiting any gene up-regulated by a MEF2 family member however there is no specific guidance to what these genes specifically are (noting the specification teaches that fetal genes are affected), and like MEF2 no guidance on the sequences. While what is known in the art does not have to be taught in a specification, the present invention encompasses a method of treatment, and a review of the art of record does not provide support that antisence sequences to MEF2 family members or sequences that inhibit fetal genes were conventional in the art. The claims are very broad in that the instantly claimed method also requires further inhibiting genes upregulated by MEF2. In this case, the instant specification does not identify any of these additional potential target genes required to practice the invention.

A "patent protection is granted in return for an enabling disclosure, not for vague intimations of general ideas that may or may be workable" (See *Genentech inc v. Novo Nordisk A/S* 42 USPQ2d 1001, at 1005). In view of the lack of guidance, working examples, breadth of the claims, the level of skill in the art and state of the art at the time of the claimed invention was made, it would have required undue experimentation to make and/or use the invention as claimed. Therefore, for the reasons above and of record, the rejection is maintained.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach